

REMARKS

In response to the Office Action mailed October 25, 2007, Applicants submit the following remarks. The one month extended deadline for filing a response is February 25, 2008. Applicants submit herewith a one-month Petition for Extension of Time and the appropriate fee. Applicants believe that this response is being timely filed. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fees to Deposit Account No. 23-2415, referencing Docket No. 31747-705.201. Reconsideration of the subject application is respectfully requested.

In view of the remarks and amendments submitted herein, Applicants believe that the Application is in condition for allowance and such action is earnestly solicited.

Claim Rejection – 35 U.S.C. § 102/§ 103

Claims 2, and 6-12 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brooks et al. (U.S. Patent No. 7,122,635), hereinafter “the ‘635 patent.” These rejections are respectfully traversed for at least the following reasons.

A reference is only good for what it clearly and definitely discloses. As noted by the Federal Circuit, anticipation under 35 U.S.C. § 102 occurs only “when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference.” *Crown Operations International, Ltd. v. Solutia, Inc.*, 289 F.3d 1367 (Fed. Cir. 2002). “A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim.” *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 (Fed. Cir. 2002). Moreover, the “single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116 (Fed. Cir. 2002). See also *In re Spada*, 911 F.2d. 705, 708 (Fed. Cir. 1990) (stating that “the reference must describe the applicant’s claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it.”); *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558 (Fed. Cir. 1996) (“To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.”).

The Official Action appears to allege that the '635 patent anticipates the present claims based on inherency. It appears that the Examiner is taking the position that a denatured collagen type-IV selective peptide antagonist comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L is an inherent characteristic of the antagonists disclosed in the '635 patent. It is respectfully submitted that the Official Action fails to meet the burden of proof required by the Patent Office for a rejection based on inherency as set forth in MPEP § 2112.

In setting the burden that must be met in a rejection based on anticipation by inherency the Patent Office provides the following guidance:

IV. EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). (See www.uspto.gov/web/offices/pac/mpep/documents/2100_2112.htm#sect2112)

Here the Official Action provides no rationale or evidence to show that antagonists disclosed in the '635 patent inherently comprise a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L. It would appear that the Official Action asserts that the present antagonists are species that

are anticipated by a genus disclosed in the '635 patent. However, the Office Action does not meet the requirements set forth in MPEP 2131.02 for "Genus-Species Situations." As set forth in the MPEP:

"[w]hen the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated."

Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Here the Office Action offers no evidence or reasoning to show that one of ordinary skill in the art is able to "at once envisage" the specific compound comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L within a generic chemical formula, assertedly disclosed in the '635 patent.

Accordingly, withdrawal of the '102 rejection based on the '635 patent is in order and is respectfully requested.

In view of the deficiencies of the rejection under 35 U.S.C. § 102, the Office Action asserts that the claimed invention is obvious over the '635 patent. Applicants respectfully, but strenuously traverse the rejection. The Office Action fails to set for a *prima facie* case of obviousness against the present claims based on the '635 patent.

By resorting to inherency arguments or to Applicants' own disclosure the Office Action relies on impermissible hindsight gleaned from Applicants' invention. Simply put, hindsight gleaned from Applicants' own disclosure cannot and should not form the basis for the requisite motivation to combine the references to arrive at Applicants' claimed invention.

Applicants respectfully submit that the improper reliance on inherency arguments and/or on Applicants' own disclosure is in direct contradiction with the standard set forth for a rejection under 103(a).

Accordingly, withdrawal of the 103 rejection based on the '635 patent is in order and is respectfully requested.

CONCLUSION

In view of the remarks and amendments submitted herein, Applicants believe that the Application is in condition for allowance and such action is earnestly solicited.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2337.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation



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Samir Elamrani, Agent for Applicants
Registration No. 43,601

650 Page Mill Road
Palo Alto, CA 94304-1050
Customer No. 021971